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George J. Christ

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EXAMINER

NGUYEN, QUANG

ART UNIT

PAPER NUMBER

1633

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/579,705	<b>Applicant(s)</b> CHRIST ET AL.	
	<b>Examiner</b> QUANG NGUYEN, Ph.D.	<b>Art Unit</b> 1633	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,7,9,11,12,15,19-23,25,27-33,35,36,38 and 42-44 is/are pending in the application.
- 4a) Of the above claim(s) 12,15,23,31,32,38 and 42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,7,9,11,19-22,25,27-30,33,35,36,43 and 44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/17/2010</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's amendment filed on 8/17/2010 was entered.

Claims 1, 7, 9, 11-12, 15, 19-23, 25, 27-33, 35-36, 38 and 42-44 are pending in the present application.

Applicants elected previously without traverse of Group I in the reply filed on 4/21/2010. Applicants further elected the following species: (a) penile smooth muscle; (b) maxi K as the elected potassium channel protein; (c) naked DNA transfer; and (d) erectile dysfunction.

Claims 12, 15, 23, 31-32, 38, 42 were withdrawn previously from further consideration because they were directed to non-elected species.

Accordingly, amended claims 1, 7, 9, 11, 19-22, 25, 27-30, 33, 35-36 and 43-44 are examined on the merits herein **with the above elected species**.

### ***Information Disclosure Statement***

It is noted that certain documents cited in the IDS filed on 8/17/2010 are entirely in Japanese. These documents were considered even though the examiner has absolutely no knowledge in Japanese.

### ***Response to Amendment***

1. The rejection under 35 U.S.C. 112, first paragraph, was withdrawn in light of Applicant's amendments, particularly with the limitations "direct introduction" and "enhance penile or urinary bladder smooth muscle relaxation". Moreover, Applicants

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stated "The claims have herein above been amended to specify that the regulation of smooth muscle tone is enhanced smooth muscle relaxation and that the route of administration of the DNA sequence is direct introduction of the DNA sequence to smooth muscle cells" (page 7, last paragraph).

2. The rejection under 35 U.S.C. 102(b) as being anticipated by Geliebter et al (US 6,150,338; IDS) was withdrawn in light of Applicant's amendment, particularly that currently amended claims recite specifically "SMAA promoter".

3. The rejection under 35 U.S.C. 102(e) as being anticipated by Geliebter et al (US 7,030,096; IDS) was also withdrawn in light of Applicant's amendment, particularly that currently amended claims recite specifically "SMAA promoter".

### ***Claim Objections***

Claim 9 is objected to because of the phrase "wherein the potassium channel protein **modulates relaxation** of corporal smooth muscle". As written, this phrase is not consistent with all of the limitation of independent claim 1 from which claim 9 is dependent on.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Amended claims 1, 7, 9, 11, 19-20, 22, 25, 27-30, 33, 35-36 and 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geliebter et al (US 6,150,338; IDS) in view of Leiden et al (US 6,436,907) for the same reasons as already set forth in the Office action dated 5/19/2010 (pages 12-13).

With respect to the elected species and within the scope of enablement, Geliebter et al teach at least a method for enhancing corporal smooth muscle relaxation resulting in a more easily attained erection in a subject, including a subject having erectile dysfunction resulted from a variety of disorders including neurogenic, arteriogenic and veno-occlusive dysfunctions, said method comprises directly injected into corporal smooth muscle cells of said subject with a DNA encoding a maxi-K potassium channel protein (hslo cDNA) in various forms, including a naked DNA expression plasmid vector, and wherein the expression plasmid vector can contain smooth muscle specific promoters and enhancers for expressing the encoded maxi-K potassium channel protein (see at least Summary of the Invention; particularly col. 4,

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lines 16-24, lines 53-65; col. 5, lines 24-44; col. 6, lines 9-49; examples and issued claims).

Geliebter et al do not teach specifically the use of a smooth muscle alpha actin (SMAA) promoter for expressing the encoded maxi-K potassium channel protein, even though Geliebter et al teach explicitly using smooth muscle specific promoters and enhancers.

At the effective filing date of the present application (11/26/2003), Leiden et al already taught at **least the use of a smooth muscle alpha-actin promoter for expressing a desired gene product into vascular smooth muscle cells in both *in vitro* and *in vivo*** (see at least Brief Summary of the Invention; particularly col. 9, line 49 continues to line 11 of col. 10).

Accordingly, it would have been obvious for an ordinary skilled artisan to modify the method taught by Geliebter et al by also selecting a smooth muscle alpha-actin promoter for expressing hslc cDNA in corporal smooth muscle cells in light of the above teachings of Leiden et al.

An ordinary skilled artisan would have been motivated to carry out the above modification because a smooth muscle alpha-actin promoter has been used to express a desired gene product in smooth muscle cells as taught by Leiden et al. Furthermore, please note that Geliebter et al already taught explicitly that any smooth muscle specific promoter can be used.

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An ordinary skilled artisan would have a reasonable expectation of success in light of the teachings of Geliebter et al., Leiden et al; coupled with a high level of skill of an ordinary skilled artisan in the relevant art.

Therefore, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Geliebter et al (US 6,150,338; IDS) in view of Leiden et al (US 6,436,907) as applied to claims 1, 7, 9, 11, 19-20, 22, 25, 27-30, 33, 35-36 and 43-44 above, and further in view of pEYFP Vector Information from Clontech (Catalog #6004-1, 2002, pages 1-3). ***This is a modified rejection necessitated by Applicant's amendment.***

The combined teachings of Geliebter et al and Leiden et al were already presented above. However, none of the cited references teaches specifically the use of an EYFP vector, even though Geliebter et al disclose that vectors suitable for the expression of hslc cDNA under the expression control of a smooth muscle specific promoter would be apparent to one skilled in the art and they include pET-3d, pcDNA, pcDNA3, pREP10, pRc/CMV among others (col. 5, line 59 continues to line 8 of col. 6).

At the effective filing date of the present application (11/26/2003), pEYFP vector was already commercially available from Clontech and its description was available in the Catalog #6004-1.

Accordingly, it would also have been obvious for an ordinary skilled artisan to further modify the method resulting from the combined teachings of Geliebter et al and

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Leiden et al, by also having an expression cassette of hslc cDNA under the expression control of a smooth muscle specific promoter such as SMAA promoter to be in a pEYFP vector.

An ordinary skilled artisan would have been motivated to further carry out the above modification because pEYFP vector was already commercially available from Clontech. Furthermore, please note that Geliebter et al already taught explicitly that any suitable vector for expression from a variety of sources can be used and that it would be apparent to one skilled in the art.

An ordinary skilled artisan would have a reasonable expectation of success in light of the teachings of Geliebter et al., Leiden et al., pEYFP Vector Information from Clontech; coupled with a high level of skill of an ordinary skilled artisan in the relevant art.

Therefore, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

### ***Response to Arguments***

Applicants' arguments related to the above rejections in the Amendment filed on 8/17/2010 (pages 9-11) have been fully considered but they are respectfully not found persuasive for the reasons discussed below.

Applicants argue basically that Geliebter et al do not teach the use of a SMAA promoter; while Leiden et al do not teach methods to treat penile or bladder smooth

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muscle and Leiden et al prefer a different promoter for cardiac muscle (col. 3, lines 16-23). Applicants also directed the examiner to the post-filing Melman et al (2008) article which compares the effectiveness of two vectors: pVAX-hSlo vector (the hSlo gene is driven by the CMV promoter) and the pSMAA-hSlo vector (the hSlo gene is driven by SMAA promoter); and shows that approximately twice as much gene is expressed from the SMAA promoter compared with the CMV promoter as was demonstrated using corporal smooth muscle cells in vitro (Table 1 on page 365). Additionally, the ability of pSAA-hSlo transfection to restore erectile function in the aging rat model of erectile dysfunction in vivo was similar to or statistically better than pVAX-hSlo (Figures 2-5, Table 2). Applicants also directed the examiner to another post-filing Christ et al (2008) article which demonstrated dramatic improvements in erectile function and sexual behavior following treatment with pSMAA-hSlo in cynomolgus monkeys with erectile dysfunction secondary to diet-induced atherosclerosis. Applicants argue that the advantageous effects of pSMAA-hSlo treatment compared to treatment using a viral vector were not predictable prior to the present invention since it was not clear if lower levels of the gene encoding the potassium channel protein would be expressed using SMAA than with a viral promoter; and that it might have been the case that gene expression in multiple cell types contributes to efficacy of treatment and therefore smooth muscle restricted expression using SMAA may not have improved erectile function as effectively as with a non-specific viral promoter.

First, please note that the above rejections were made under 35 U.S.C. 103(a); and therefore none of the cited references has to teach every limitation of the instant

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claims. Moreover, Geliebter et al already teach explicitly at least a method for enhancing corporal smooth muscle relaxation resulting in a more easily attained erection in a subject, including a subject having erectile dysfunction by **directly injected into corporal smooth muscle cells of said subject with a DNA encoding a maxi-K potassium channel protein (hslo cDNA) operably linked to a smooth muscle specific promoter**; and that Leiden et al specifically stated “**A preferred vascular smooth muscle specific enhancer promoter is an endothelin promoter or a smooth muscle  $\alpha$ -actin promoter**” (see at least col. 3, lines 20-23; and issued claims 21-22).

Second, with respect to the results obtained in the post-filing Melman et al article (2008) it is noted that the comparison is specifically between the use of two specific vectors pVAX-hSlo (expression is driven by a CMV promoter) and pSMAA-hSlo (expression is driven by a SMAA promoter); and that the pVAX-hSlo plasmid vector also has a replacement of an ampR gene by a kanR gene. However, the instant claims are not required to the use of the same pSMAA-hSlo vector as disclosed in the post-filing Melman et al article. Moreover, it is also noted that only claims 43-44 recite the limitations "at least as effective in enhancing relaxation of the smooth muscle in a subject as using a viral promoter operably linked to the DNA sequence encoding the potassium channel protein" and "at least as effective in treating erectile dysfunction in a subject as using a viral promoter operably linked to the DNA sequence encoding the potassium channel protein", respectively; and such limitations do not necessarily limit to a comparison specifically to the pVAX-hSlo plasmid vector used in the post-filing

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Melman et al article. Furthermore, it is noted that Melman et al stated "**Another potential issue is that the pSMAA-EYFP vector-derived pSMAA-hSlo construct may have different expression characteristics as compared to the pVAX-derived vector**" (page 367, 2<sup>nd</sup> col., last paragraph). Thus, the specific backbone of an expression vector may also influence expression characteristics of a particular transgene. The post-filing Christ et al article (2008) simply demonstrated therapeutic results obtained via the use of the pSMAA-hSlo in cynomolgus monkeys with erectile dysfunction secondary to diet-induced atherosclerosis.

Third, there is nothing that is unpredictable or unexpected for the methods as claimed broadly. This is because Geliebter et al already teach explicitly a method for enhancing corporal smooth muscle relaxation resulting in a more easily attained erection in a subject, including a subject having erectile dysfunction by **directly injected into corporal smooth muscle cells of said subject with a DNA encoding a maxi-K potassium channel protein (hslo cDNA) operably linked to a smooth muscle specific promoter**. Moreover, Geliebter et al also stated explicitly "Recent studies by the inventors have indicated that **hyperpolarization of corporal smooth muscle cells via activation of potassium channels represents an important mechanism for controlling corporal smooth muscle tone**" (col. 13, see at least lines 52-55; and the section entitled "Potassium channels and corporal smooth muscle function: Evidence that altering K channel function can increase "sensitivity" to relaxation"). Furthermore, at the effective filing date of the present application (11/26/2003) Dean et al (US 6,130,207) already demonstrated that **the smooth muscle specific promoter SMGA**

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**(smooth muscle gamma-actin) promoter is cell-specific and relatively stronger than the viral SV40 promoter** (see at least Fig. 7). Parmacek et al (US 6,114,311) also showed that **the smooth muscle specific promoter SM22 $\alpha$  promoter is at least as active as the viral pRSVL promoter in smooth muscle cells** (see at least Fig. 1B and Fig. 2).

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory

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double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 7, 9, 11, 19-22, 25, 27-30, 33, 35-36 and 43-44 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over either claims 1-9 of U.S. Patent No. 6,150,338 or over claims 1-3 of U.S. Patent No. 7,030,096 and in view of Leiden et al (US 6,436,907) and pEYFP Vector Information from Clontech (Catalog #6004-1, 2002, pages 1-3). ***This is a modified rejection necessitated by Applicant's amendment.***

Claims 1-9 of US Patent No. 6,150,338 are drawn to a method for inducing penile erection in a subject comprising the introduction and expression of a DNA sequence encoding a maxi-K potassium channel protein into a sufficient number of penile cells of the subject to induce penile erection in the subject.

Claims 1-3 of US Patent No. 7,030,096 are directed to a method of enhancing relaxation of a penile smooth muscle in a subject having heightened contractility of the penile smooth muscle, comprising the direct introduction and expression of a DNA sequence (in the form of a naked DNA) comprising a promoter sequence, including a smooth muscle specific promoter, operably linked to a sequence encoding maxi-K

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potassium channel protein into a sufficient number of penile smooth muscle cells of the subject.

The claims of the present application differ from the issued claims of either US Patent No. 6,150,338 or US Patent No. 7,030,096 in reciting specifically using the smooth muscle specific promoter SMAA. Claim 21 of the present application further recites specifically that the DNA sequence is present in an EYFP vector.

However, at the effective filing date of the present application (11/26/2003) Leiden et al already taught at **least the use of a smooth muscle alpha-actin promoter for expressing a desired gene product into vascular smooth muscle cells in both *in vitro* and *in vivo*** (see at least Brief Summary of the Invention; particularly col. 9, line 49 continues to line 11 of col. 10).

Additionally, at the effective filing date of the present application (11/26/2003) pEYFP vector was already commercially available from Clontech and its description was available in the Catalog #6004-1.

Accordingly, it would have been obvious for an ordinary skilled artisan to modify the method taught by either US 6,436,907 or US 7,030,096 by also selecting a smooth muscle alpha-actin promoter for expressing hslo cDNA in corporal smooth muscle cells; as well as using the pEYFP vector.

An ordinary skilled artisan would have been motivated to carry out the above modifications because a smooth muscle alpha-actin promoter has been used to express a desired gene product in smooth muscle cells as taught by Leiden et al. Moreover, please note that both US 6,436,907 and US 7,030,096 already taught explicitly that any

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smooth muscle specific promoter can be used. Furthermore, pEYFP vector was already commercially available from Clontech.

An ordinary skilled artisan would have a reasonable expectation of success in light of the teachings of either US 6,436,907 or US 7,030,096; Leiden et al and pEYFP Vector Information from Clontech; coupled with a high level of skill of an ordinary skilled artisan in the relevant art.

Therefore, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

### ***Response to Arguments***

Applicants' arguments related to the above rejections in the Amendment filed on 8/17/2010 (pages 11-12) have been fully considered but they are respectfully not found persuasive for the reasons discussed below.

Applicants simply requested a withdrawal of the above rejections based on the same arguments presented for the above 103 rejections.

Please refer to the Examiner's responses to Applicant's same arguments for the above 103 rejections.

*The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.*

Shimizu et al (J. Biol. Chem. 270:7631-7643, 1996) characterized the smooth muscle alpha-actin gene promoter.

### ***Conclusions***

#### ***No claim is allowed.***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's SPE, Joseph T. Voitach, Ph.D., may be reached at (571) 272-0739.

**To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.**

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**Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.**

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

/Quang Nguyen/

Primary Examiner, AU 1633